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July 31, 2003

Human Health Risk Assessment Peer Review Panel
c/o Ms. Alison Wolfe
MNG Center at SRA
2801 Clarendon Boulevard, Suite 100
Arlington, Virginia 22201

Re: The Massachusetts Department of Environmental Protection's Technical Review Comments on EPA's June 6, 2003 *Human Health Risk Assessment GE/Housatonic River Site Rest of the River*

Dear Peer Review Panel Members:

The Department of Environmental Protection (DEP) has reviewed the report titled *Human Health Risk Assessment GE/Housatonic River Site Rest of the River*, prepared by Weston Solutions, Inc. for the U.S. Environmental Protection Agency, dated June 6, 2003. DEP understands that this monumental document represents the culmination of five years of intensive and comprehensive fieldwork, and thoughtful and detailed debate and deliberation by a dedicated work group. Overall, DEP concurs with the methodologies employed and the conclusions reached in the risk assessment, but is providing some recommendations as to how the risk assessment might be improved.

This letter summarizes comments by Nancy Bettinger and Thomas Angus, risk assessors from our Office of Research and Standards (ORS), who performed as complete a review of the document as time constraints would allow and provided risk assessment expertise on behalf of the project managers in the Bureau of Waste Site Cleanup Western Regional Office Special Projects Unit.

DEP offers the following comments for the Peer Review Panel's consideration. These comments are divided into four sections: 1) Human Health Risk Assessment GE/Housatonic River Site Volume I, 2) Phase II Direct Contact Risk Assessment Volume IIIA, 3) Consumption Of Fish And Waterfowl Risk Assessment Volume IV, and 4) Agricultural Product Consumption Risk Assessment Volume V. Please see Attachment A for the list of references cited in this letter.

HUMAN HEALTH RISK ASSESSMENT GE/HOUSATONIC RIVER SITE VOLUME I

Attachment 2 Congener vs. Aroclor Regression Analysis. The risk assessment uses regression to estimate congener concentrations based on total aroclor data. The text explaining the correlation between total polychlorinated biphenyls (PCBs) and congeners is extremely brief. The risk assessment should

consider using the upper 95% confidence limit on the regression lines in the risk assessment rather than best estimate values. Use of the best estimate values does not appear to be justified by the quality and quantity of the available data.

It would be useful to also perform the regression with Reach 6 data and to compare the regression lines for Reaches 5 & 6. Transport of PCBs down the river may alter the relative composition of congers, dioxins, and furans. If the regression lines are similar in Reaches 5 & 6, then it would confirm the validity of the applying Reach 5 regression lines to Reach 6. If the results are different, then it may be appropriate to perform the risk assessment using separate regression analyses for Reaches 5 & 6.

There is a great deal of variability in the concentrations of individual congeners (or dioxins or furans) versus total aroclors. Data are presented in a log-log plot and individual data points can be an order of magnitude different from the regression line at a given total aroclor concentration. This variability is briefly discussed in Appendix D. This variability and its potential effects on the overestimation or underestimation of risk should be discussed in an uncertainty analysis.

In addition to regressions plots to correlate individual congeners and total aroclors, Attachment 2 should include regression analysis for total congeners versus total aroclors. A regression of total congeners versus total aroclors would allow the reader to determine how well congeners and aroclors generally correlate. The report should discuss whether total congeners or total aroclors give a consistently higher concentration of PCBs.

Editorial Comments: Regression plots should be labeled to indicate whether they represent 2002 data or all data combined. The text should discuss each of the graphs presented in Appendix D in more detail.

PHASE II DIRECT CONTACT RISK ASSESSMENT VOLUME IIIA

Future Use. DEP recommends that the most conservative recreational scenario be applied when evaluating future use in non-residential areas of the floodplain. There are many factors that make the prediction of future use extremely difficult. The location of the river channel may shift. Areas that are frequently flooded now may be drier in the future. Successional changes may occur in vegetation, causing areas to be easier to access as dense brush is shaded out by trees. Property owners may remove vegetation or develop access roads or trails. Because of the uncertainties of future use, DEP recommends that the most conservative exposure scenario be applied to all exposure areas in future use scenarios. The young child exposure scenario appears to currently be the most conservative and should be applied at all properties.

Exposure Point Concentration Calculations. The method for calculating exposure point concentrations is not transparent or reproducible. Inverse distance weighting (IDW) was used to populate a grid using the sampling data. Depending on the distribution of the data, the 95% UCL was calculated using the t-statistic (for normally distributed data), Land's method using the H-statistic (for lognormally distributed data) or Hall's modified bootstrap procedure (for data that was neither normally nor lognormally distributed). Professional judgment was used in some cases when a nearest neighbor from the same habitat type was not available for calculating polygon concentrations. The exposure point concentrations are impossible to check for accuracy. DEP is in favor of using spatial averaging and our risk assessment guidance (DEP 1995) discusses the use of spatial averaging. However, DEP would prefer that spatial weighting be performed using a methodology that is more transparent and reproducible. Also, the report

should discuss whether the original data or the populated grid were used to determine whether the data were normally or lognormally distributed.

This assessment uses a "Hall's modified bootstrapping" technique to estimate concentration distributions in some areas. Bootstrapping can be used to approximate confidence limits for the population mean by using a random sampling program to iteratively re-sample from the small data set available. Page 4-18 states: "bootstrap procedures assume that samples are representative of the underlying distribution of concentrations." Bootstrapping cannot account for sampling error, however, so using bootstrapping techniques may underestimate (or overestimate) concentrations in many cases. Therefore, bootstrapping does not necessarily provide a conservative estimate of the mean, as do the t-statistic and Land's method using the H-statistic.

DEP does not support the use of bootstrapping. Although it has been posited that bootstrapping can be used to estimate confidence limits on the population mean from a small sample, the technique ignores sampling error. Since sampling error is the major source of uncertainty in estimating a population mean from a small sample, there is little reason to expect bootstrapping to reduce or illuminate the uncertainty about the estimated mean or estimated confidence limits. Bootstrapping should not be used for exposure areas with small sample sizes. The report does not currently document where Hall's bootstrapping was applied, so the reader cannot determine if it was used in cases of small sample sizes. The report should document the distribution shapes and 95% UCL techniques used for each exposure area and subarea.

The report should discuss the available number of samples, and the possibility that concentrations may have been significantly underestimated. Hall's modified bootstrap procedure should be discussed in detail in the text, including its tendencies to either overestimate or underestimate the true mean.

Exposure Points (Exposure Areas). Averaging over large areas should only be done when appropriate. This is an acceptable practice if exposure is equally likely to occur throughout the area over time, or if the concentration distribution over the smaller areas was the same as that over larger areas. However, in areas where concentrations vary significantly, and where a person's exposure may be restricted to smaller areas, this approach is not appropriate.

In this assessment, a number of the recreational exposure points are very large (as large as 100 acres). Further, from inspecting the maps included in the report, it appears that the landscape features, such as wetlands, within many of these larger areas may promote uses of smaller areas and discourage movement from among portions of the larger areas. Further, landscape features in the vicinity of many riverbank exposure areas, such as roads and small residential neighborhoods, suggest that people would preferentially use specific smaller areas for recreational activities. For instance, Exposure Area 40 is 102.6 acres. Houses are located in the northeastern corner of Exposure Area 40 in Figure 5-40. It is unreasonable to assume that recreational visitors from these homes would range over the entire 102 acres randomly. They are much more likely to spend time in the northern portion of this parcel closer to their home. The 102-acre parcel contains high PCB concentrations including a maximum detected concentration of 162 mg/kg. A person using more contaminated portions of the northern part of the Exposure Area may be at significantly higher risk than the risk calculated for all of Exposure Area 40. If exposures are likely to occur in a smaller area, then the smaller area should be evaluated for risk as a separate exposure point. Otherwise, high contaminant levels could be left unremediated in some high-use areas.

Residential and industrial exposure points identified in this report are also larger than the size of the areas people are actually likely to use. In some cases, exposure points include multiple tax parcels. Since a

house or industrial site would exist on a single tax parcel, and the exposure would occur on that single tax parcel, averaging across parcels may mask risks at individual parcels. In some recreational areas exposure may also occur in a relatively small area, such as a formal or informal play area, or an accessible tract of undeveloped land next to a residential area.

Section 7.2.2.1 states that "if an individual's exposure occurs across a smaller area, where soil concentrations exceed the estimated mean concentration for the entire exposure area, risks may be underestimated." DEP believes that this is a significant problem in the risk assessment. Many of the exposure areas are larger than an individual's exposure could reasonably be expected to occur over. However, DEP also recognizes that the large size of the site and the fact that it may be very difficult in some of the more remote larger exposure areas to ascertain and/or differentiate existing patterns of use, may make subdivision of some larger current exposure areas difficult in some portions of the site. Therefore, DEP recommends that, where feasible, current exposure areas be broken down into reasonably sized exposure units based on topography. If it is difficult to determine appropriate exposure units based on topography, a maximum exposure area size could be used. For example, for Removal Actions Outside the River, the Consent Decree designates a maximum exposure area size of 0.5 acre for commercial and recreational properties and 0.25 acre for residential properties. DEP believes that a maximum exposure area size should be implemented in the human health risk assessment. Using smaller exposure areas is consistent with DEP regulations and guidance. The Massachusetts Contingency Plan states: "The identification of receptors, Site Activities and Uses, Exposure Points and Exposure Point Concentrations shall be conducted in a manner which provides a conservative estimate of the exposure to oil and /or hazardous material which a receptor may receive over time (310 CMR 40.0920). The *Guidance for Disposal Site Risk Characterization* (DEP 1995) states that an exposure point should be "an area within which the receptor has an equal likelihood of exposure." DEP believes that exposure areas should be further broken down into areas that meet this criterion.

Editorial Comment: Exposure area figures should clarify whether IDW PCB concentrations depicted in difficult/wadable areas are already reduced by a factor of 50% to account for differing accessibilities.

Accessibility Classifications and Use-Weighting. Section 4.4.1.1.1. To account for difficult-to-access areas, concentrations were reduced in these areas by 50%. The report refers to this as use-weighting. Averaging within an exposure area should assume equal exposure across the area. Depending on the relative concentrations in different areas, this procedure could underestimate actual exposures. DEP believes that if exposures within an exposure area are different, then it should be broken into separate exposure areas.

CONSUMPTION OF FISH AND WATERFOWL RISK ASSESSMENT VOLUME IV

In July of 1997, DEP and EPA provided technical review and comments on the General Electric Company's (GE's) February 14, 1996 *Proposal for Human Health Risk Assessment* (hereafter referred to as the July 1997 comments). Some of the joint agency comments from this 1997 document are presented below. DEP believes that the risk assessment should be consistent with these previous comments except where there is new contrary information or agency policies have changed.

Dioxin-like PCBs. In a previous draft of the risk assessment, values from EPA's draft dioxin reassessment were used to calculate risks. However, in the public draft, the draft dioxin cancer slope factor (CSF) is presented, but estimated risks are not included. DEP believes that the risks estimated using the draft dioxin numbers should be presented and discussed in the uncertainty analysis.

Skin-on Versus Skin-off Filets. Section 4.3.3.1. The state of Massachusetts typically collects skin-off filets for analysis. However, there has been recent discussion among Massachusetts agencies to collect skin-on fillets or whole-body data, since cooking preferences vary and some people do not remove the skin prior to cooking. The fish data set included only skin off, fat-trimmed fillet data. The risk assessment assumes that only skinned and trimmed filets are consumed. However, fish filets are often cooked with the skin on and the skin is removed afterwards. The skin contains more lipid than the meat and therefore likely has higher levels of lipophilic chemicals like PCBs and dioxins. Because these chemicals are likely to migrate from the skin to the meat during cooking, the skin-off filet data may underestimate exposures. Also, some individuals may consume drippings from the skin, or even the skin itself. Therefore, current skin-off fish data set may underestimate consumption exposure. The risk assessment should attempt to provide estimates of risk for consuming skin-on fish fillets using any available skin-on fillet data or conversion factors derived from the literature.

Cooking Loss. DEP does not believe that cooking loss should be included in any estimates of risk (including the central tendency estimate) in the risk assessment. In the July 1997 comments, DEP and EPA stated that the reduction in PCB concentrations in fish caused by cooking is not a true "loss" because although some PCBs may volatilize during cooking, most of the PCBs will remain in the fat drippings. For this reason, DEP still does not believe a cooking reduction factor is justified.

Calculation of Exposure Point Concentrations. In Section 4.4, bootstrapping is used to estimate tissue concentrations in the report when the data are neither normal nor lognormal. However, bootstrapping is inappropriate in small data sets because it is merely sampling with replacement. If the small number of samples is not representative of the location of the distribution, then bootstrapping could significantly over- or underestimate the EPC.

Probability Bounds Analysis. Based on DEP's reading of the report and background material provided by Scott Ferson, DEP believes that probability bounds analysis is useful in evaluating uncertainty if the probabilistic risk assessment is used. It is difficult to follow descriptions of how the probability bounds analysis was performed using the RAMAS software. In the final risk assessment, the probability analysis discussion should be more transparent and reproducible. To the extent possible, the report should explain all steps in the analysis and the procedures performed by the RAMAS software. The report should discuss the role of professional judgment in performing the probability bounds analysis.

Diving Ducks. The uncertainty analysis discusses the fact that there is no tissue data for diving ducks and they would likely have higher dietary exposures than dabbling/perching ducks. The report should discuss whether diving ducks are year-round residents and have the potential to accumulate PCBs year-round in the Housatonic River. The uncertainty analysis should provide a discussion of potential tissue concentration differences among different types of ducks.

Frogs' Legs Data. A previous version of the report mentioned that data for frogs' legs had been collected, but did not provide the data. This discussion was removed from the current version of the report. The report should summarize the data for tissue analysis of frogs' legs and provide a reference to the report containing the data.

Turtle Harvesting. The current version of the report does not discuss turtle harvesting. A previous version of the report had stated that there is no indication that turtles are currently being harvested for consumption. However, DEP was told by EPA and its consultants that there is anecdotal evidence that

someone has been harvesting turtles and selling them for meat. This should be resolved and discussed in the report.

Target Population of the Probabilistic Risk Assessment. In the July 1997 comments, DEP and EPA previously commented that the evaluation of exposure to recreational anglers from ingesting contaminated fish should focus on the subgroup of anglers who eat a relatively large amount of fish from the water body of concern. Thus the fish consumption rate should represent an average or typical intake rate for this "high-use" group. DEP still believes that the risk assessment should be focused on hunters -use" end of the curve rather than on the average recreational hunter or angler. DEP does not believe that the probabilistic risk assessment evaluates the high-use group. Input distributions are based on the whole angler population rather than the high-use angler. Choosing a conservative upper bound on the recreational angler risk distribution is not necessarily protective of high-use anglers. DEP's concerns about this analysis include:

The data set used in determining meal frequency is based on recreational fishermen in general rather than high end users. In a point estimate risk assessment, the risk is calculated for the individual who represents a high-end user (i.e., 95th percentile of the ingestion frequency). However, the exceedance probability distribution developed in the probabilistic risk assessment estimates the risk to the recreational fishing population in general, rather than the high end users specifically. The microexposure analysis fails to evaluate high end users in terms of meal frequency, fish concentration, and cooking method.

The microexposure modeling is performed as if there is no relation between meal frequency from one year to the next, no relationship between concentration from one meal to the next, and no relationship between cooking method from one meal to the next. Clearly, people are not random in many of their behaviors. A person who cooks their fish a certain way one time is more likely to cook their fish that same way for subsequent meals. An individual that has a favorite cooking method that happens to result in a low cooking loss would have their exposure underestimated by this assessment.

The analysis does not capture the fact that people tend to have favorite fishing spots. It assumes random selection of fishing locations. An individual who fishes a favorite spot that has elevated levels of contaminants in sediment and therefore elevated levels of contaminants in fish is likely to be repeatedly exposed to high levels of fish when compared with the random case.

The Monte Carlo analysis does not capture the high-end fish consumer sufficiently. The program randomly picks meal frequencies yearly for the given exposure duration of the individual. However, individuals are not random in terms of fish meal frequency. An individual who enjoys consuming recreationally caught fish and eats them at a high meal frequency one year is likely to continue to eat sport-caught fish meals at a high rate the following year. By assuming that meal frequency is random, the Monte Carlo assessment does not capture the high-end consumer.

If distributions could be developed for the high-end user, then Monte Carlo analysis would represent the exposures for high-use fish consumers, but they do not, as currently constructed. There is no correspondence between the 95th percentile on the Monte Carlo curve and a high-end user. There are only probabilities for the individual whose fishing and fish consumption behavior is random from year to year, rather than preference-based. The probability bounds analysis evaluates incertitude and variability, and evaluates dependency between variables. However, the probability bounds analysis does not appear to capture the likelihood that an individual who consumes fish with a high frequency one year is likely to consume fish with a high frequency in subsequent years.

In summary, the point estimate and probabilistic risk assessment do not protect the same target population. The text should explain the integration of the point estimate and probabilistic risk assessments more clearly. The risk assessment should clearly compare the receptors evaluated in the point estimate risk assessment and the probabilistic risk assessment and discuss how the estimates of risks compare.

Subsistence Fishing. In the July 1997 comments, DEP and EPA also stated that GE should evaluate risks to subsistence fisherman as part of the risk assessment. The agencies recommended a reasonable maximum exposure (RME) fish ingestion rate of 140 g/day. DEP and EPA also stated that, if further investigation showed that subsistence fishing is not practiced and would not be reasonably foreseeable in the future, then subsistence fishing estimates need not be considered in risk management decisions. The report briefly discusses a lack of evidence for current subsistence fishing, but does not quantitatively evaluate the risks, particularly for foreseeable future uses. In addition, there is a high level of interest and concern among members of the public about the risks associated with subsistence fishing. DEP believes that the risk assessment should provide such information to the public and that subsistence fish ingestion should be included quantitatively.

Endocrine Disruptor Effects of PCBs. In the July 1997 comments, DEP and EPA recommended that, as part of the uncertainty section of the risk assessment, the endocrine disruption potential of PCBs should be addressed. The agencies referred GE to Attachment C of their comments, which reflected the agencies' views on potential endocrine disrupting effects. The report does not currently discuss endocrine disruptor effects.

AGRICULTURAL PRODUCT CONSUMPTION RISK ASSESSMENT VOLUME V

The July 1997 comments also addressed agricultural exposures and some of these comments are presented below. A great deal of thought and discussion went into the preparation of these earlier joint agency comments. The risk assessment should be generally consistent with these earlier joint agency comments, unless there are specific reasons to depart from earlier positions. The following comments identify points of departure from previous positions that do not appear to be justified by new information.

General Comments

- The agricultural portion of the human health risk assessment relies heavily on modeled data. The risk assessors did an excellent job of summarizing the scientific literature and using the available data as well as they could be used in modeling concentrations in agricultural exposure pathways. However, data gaps and modeling for agricultural exposure pathways have introduced significant uncertainty into the human health risk assessment. Since the health risks from consumption of agricultural products appear to be high, DEP strongly recommends that basic analytical data for PCB and polychlorinated dibenzodioxin/polychlorinated dibenzofuran (PCDD/PCDF) congeners in cow's milk, beef, beef fat, and eggs (if available) be collected to reduce uncertainty in agricultural exposure pathways. DEP is particularly concerned about PCB concentrations in milk that is currently being distributed commercially or may be distributed in the future. DEP believes that the risk assessment should include measured concentrations in cow's milk from the existing dairy farms and use the data to evaluate uncertainty in the model and to verify predicted PCB concentrations in cow's milk.

- The report makes no attempt to characterize risks for current commercial farms or back-yard garden or animal operations. The risk assessment instead provides risks for generic farming scenarios at tPCB concentrations of 0.5 and 2 mg/kg in soil. This is a significant departure from the approach in the previous draft where site-specific risks were presented for existing farms. Since the risk assessment does not provide exposure point concentrations or even summaries of the analytical data for comparison to the generic risk levels (other than depicting concentration ranges on figures that do not identify the locations of specific current agricultural scenarios), it is very difficult to determine from this report whether exposures at existing farms pose a significant health risk. The reader has no direct means of determining if there are human health risks from agricultural exposure pathways for any location in the Housatonic River floodplain. This lack of site-specific evaluation is inconsistent with both EPA and DEP risk assessment guidance. The final report should either present health risks associated with existing farms or compare the exposure point concentrations directly to risk-based concentrations.

- Bioconcentration factors (BCFs) and transfer coefficients should not be based on averages, but instead on maximum values from site-specific studies or from well-designed studies from the literature. The site-specific uptake studies are based on small data sets (10 or fewer samples each). Studies from the literature used in the risk assessment are also based on small samples sizes. A 95% upper confidence limit would be an appropriate substitute for maximum values in cases where sufficient data are available.

- The risk assessment should summarize all studies used in the derivation of BCFs. For each study, the summary should include the number of animals, route(s) of exposure, duration of exposure, and overall quality of the study.

Specific Comments

Contaminants of Potential Concern. Section 2.2. 4,4-DDE (detected in 12/110 samples, or 11%) and 4,4-DDT (10/85 samples, or 12%) were eliminated, in part, due to a low frequency of detection. DEP does not consider 11% or 12% a "low frequency of detection".

Goat Meat. Section 4.2. Human exposure to goats was assumed to occur only through the consumption of goat's milk. Meat should also be listed as a potential pathway.

Qualitatively Evaluated Agricultural Exposure Pathways. The risk assessment evaluates a number of agricultural pathways (such as goats and sheep) qualitatively and discusses their risks relative to quantitatively evaluated pathways. This approach is acceptable, but care must be taken that risk management decisions are protective. For instance, future agricultural areas may be appropriate for a qualitatively evaluated method of farming (such as goats), but not a quantitatively evaluated agricultural exposure. Such a property would need site-specific risks calculated for the appropriate agricultural exposure pathway.

Commercial Produce. The last paragraph of Section 4.1 states that human health risks from other agricultural pathways (beyond commercial or backyard dairy, beef, and poultry and home gardens), including "commercial produce," were "considered relative to the scenarios assessed quantitatively". Section 5.1 discusses relative risks for these other pathways, including sheep, goats, deer, and wild edible plants, but not commercial produce. Section 2.1.1.5 discusses that commercial produce is currently grown in the floodplain in Reach 9, and a currently active farm used to grow squash in the floodplain in

Reach 5. DEP believes that the risk assessment should at least qualitatively address risks of commercial produce (relative to home gardens) and that a subsection on commercial produce should be added to Section 5.1.

Bioconcentration Factors (BCFs) and Transfer Coefficients. The report should discuss exposure levels used in all the BCF and transfer coefficient studies from the literature and how they compare to exposure levels likely to be found in the Housatonic River floodplain. The report notes that higher exposure levels tend to result in relatively lower BCF values. Uptake studies are often conducted with exposure levels much higher than those likely to be found in the environment. If studies were conducted at exposure levels that are higher than conditions likely found in the Housatonic River floodplain, then BCFs would likely be underestimated.

Studies used as the basis of BCF values should be summarized in the report (regarding the number of animals, route(s) of exposure, levels of exposure, duration of exposure) and the overall quality of the studies should be discussed. The level of detail should be sufficient to justify the use of the studies for deriving BCFs.

Mammalian BCFs for PCB Congeners. Given the small number of studies and small number of animals used in the studies, DEP does not believe it is appropriate to include a factor for metabolism when calculating BCFs for uptake into mammals. The report used a metabolism factor of 0.5 for the four congeners in metabolism class 2 and a factor of 1.0 for all other congeners. DEP believes that the risk assessment should assume no metabolism for any of the congeners. Since the equations were based on actual tissue data, it appears as if metabolism is already accounted for.

Mammalian BCFs for PCDD/PCDFs. Section 4.2.2.2.3. The risk assessment used mean values from three studies. However, these studies were conducted with one, four, and four cows, respectively. Given the small number of animals in these studies, and the potential for individual farmers to be exposed to a small number of animals, DEP believes it is appropriate to use maximum BCF values.

Poultry BCFs. Section 4.2.2.2.4. The section on Poultry BCFs is difficult to follow. Poultry BCFs should be presented in the same format as mammalian BCFs, where PCB mixtures, PCB congeners, and PCDD/PCDFs are presented separately. The risk assessment should be clear about which studies had data for poultry and which studies had data specific to eggs. All studies used should be summarized in the text (numbers of birds, route of exposure, duration and quality of study, etc.).

Poultry and Egg BCFs for Mixtures. The report derives BCFs for PCB mixtures from a study by Fries et al. (1977). This study was conducted using Aroclors 1254 and 1268. The report should present a summary of the study, including numbers of hens used, duration of the study, and routes of exposure (feed versus soil). The report should also discuss the analytical methods used in this older (1977) study. The report should discuss the levels of exposure to determine if they are comparable to soil levels in the Housatonic. The report earlier noted that BCF values tend to be higher for lower soil levels, and many of the studies were conducted at exposures that would be higher than those found in the Housatonic River Valley. DEP believes that given the uncertainties inherent in extrapolating between different Aroclor mixtures, the maximum BCFs from the literature should be used.

Poultry and egg BCFs for mixtures were derived by taking the average of Aroclors 1254 and 1268 to represent Aroclor 1260. Because data are not available for Aroclor 1260, DEP believes that the more conservative of the two BCFs (among Aroclor 1254 and 1268) should be chosen. The details of the

studies (number of chickens, method of exposure, length of exposure) and the quality of the studies should be discussed in the text.

Poultry BCFs for PCDD/PCDFs. The study used to derive BCFs consisted of two groups: a low-dose group fed contaminated soil from a contaminated site, and a high dose group fed the same soil spiked with some, but not all of the congeners present in the low-dose soil. The high-dose group had BCFs approximately twice those of the low-dose group. The risk assessment used BCFs from the low-dose group (or the average of the high and low-dose values, if spiking was not performed), with the rationale that the lower BCFs in the low-dose group may be due to aging of contaminants that may reduce bioavailability. DEP believes that the highest BCFs from this study should be used in the risk assessment, regardless of whether they are from soil spiked with contaminants or not. This was the only study for PCDD/PCDFs discussed in the risk assessment. There is no evidence presented in the text that the lower BCFs were due to reduced bioavailability due to aging. These lower BCFs may simply be due to sampling error or other factors. The risk assessment should be performed in a conservative manner and it is appropriate to use the most conservative BCFs when data are limited.

TCDD poultry BCF. The BCF for TCDD was reduced to reflect the spiked to non-spiked ratios of other congeners from the study used. DEP believes that TCDD BCFs should not be reduced. Data are limited and the available TCDD value should be used to reflect an appropriate level of conservatism in the risk assessment, given the limited data.

1,2,3,7,8-PCDF poultry BCF. The risk assessment assumes a poultry BCF of zero for 1,2,3,7,8-PCDF, because soil concentrations were at or below quantification limits in the study used. DEP recommends that a study with adequate soil concentrations be used to derive a BCF. EPA's *Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities* (EPA 1998) derives a 1,2,3,7,8-PCDF BCF for poultry from a study by Stephens, Petreas, and Hayword (1995). DEP recommends that this study be used to derive a TCDD BCF for poultry. If this study is deemed inappropriate, then BCFs should be derived using a mathematical model or bioaccumulation equivalency factor based on 2,3,7,8-TCDD. This methodology could also be applied to other dioxin-like compounds.

If site-specific data on poultry and egg concentrations at various soil concentrations were obtained, a great deal of uncertainty could be eliminated.

Regression Models Relating Milk Fat BCFs to Whole Egg BCFs and to Adipose Tissue. The use of these models should be discussed in the text. The procedures used and the uncertainties of the process should be discussed. The last two paragraphs of Section 4.2.2.2.4 should be organized into subsections and expanded.

Transfer of PCBs and PCDD/PCDFs to Plants. This section of the document should summarize site-specific studies used (conditions, number of samples, analytical methods, detection limits, etc.) and document any uncertainties in the data. Site-specific data should be discussed in relation to other studies in the literature, wherever possible, so that BCFs can be presented in the context of the range of values available in the literature.

Soil-to-Grass Transfer Factors. Mean grass-to-soil concentration levels were used as soil-to-grass transfer factors. Because only eight grass samples were collected from one area where concentrations are all similar, uncertainty about the representativeness of the site (relative to the rest of the floodplain) is high. Maximum grass-to-soil concentration levels should be used as soil-to-grass transfer factors.

Soil-to-Corn-Silage Transfer Factors. The text does not discuss how soil-to-corn-silage transfer factors were calculated for tPCBs using the available data (i.e., whether mean or maximum values were used). Only ten corn stalk samples were analyzed. The report should be clear that tPCB corn transfer factors were based on the 8 floodplain samples from Table 2-4. The report cites 10 samples, but two of these are reference samples. Given the limited data, DEP recommends that maximum transfer rates for tPCBs be used in the risk assessment. Congener analysis was not performed on the corn data. Because of the limited data, and the uncertainty in extrapolating from grass to corn, DEP recommends that maximum, rather than mean, soil-to-grass transfer factors for PCB congeners be used as soil-to-corn transfer factors.

Soil-to-Plant Transfer Factors for Home Garden Produce Categories. The risk assessment used "best estimates" (in contrast to upper bounds) of garden produce-to-soil concentration ratios (Section 4.3.4). The risk assessment should define the term "best estimate" (i.e., mean, median, maximum). Given the limited data available, maximum values would represent a more appropriate level of conservatism for the risk assessment. If adequate numbers of studies are available in the literature, a 95th percentile value from the range of available studies for each of the three garden produce categories (exposed fruit, exposed vegetables, and root vegetables) could be used as a soil-to-plant transfer factor. All of the site-specific studies have small numbers of samples (10 or less), and therefore DEP believes maximum transfer factors are appropriate.

The discussion of dioxin-like PCB congeners and PCDD/PCDF congeners in garden produce is inadequate. The report merely asserts that these compounds accumulate less in plants than animals and relegates their discussion to the uncertainty section without including them in exposure estimates. Estimates of PCB congeners and PCDD/PCDFs should be included in the RME estimates and should not be relegated to the uncertainty analysis.

Food Consumption Rates. The risk assessment used the 75th percentile of consumption rates rather than the 95th percentile of consumption rates as the reasonable maximum exposure. The 75th percentile was chosen because U.S. Department of Agriculture's Nationwide Food Consumption Survey (NFCS) was conducted over a short time interval (7 days) and therefore does not necessarily reflect the long-term consumption distribution. ORS disagrees with this approach. While the short time frame may skew the data, there is no reason to believe that the data are skewed high rather than low. Therefore the use of the 75th percentile may significantly underestimate a reasonable maximum exposure and is inconsistent with EPA guidance.

Preparation and Cooking Losses for Animal Products. The risk assessment assumes cooking losses for agricultural exposures. The risk assessment points out that risks to individuals regularly making gravy or beef stock would be underestimated and evaluates the effect of reducing the cooking loss factor to zero as part of the sensitivity analysis. DEP believes that it is more appropriate to assume no cooking loss in the risk assessment.

According to the sensitivity analysis, if the cooking loss were reduced to zero, cancer risks and noncancer hazard estimates associated with the commercial and backyard beef scenarios would increase by a factor of two. The sensitivity analysis does not currently discuss the effect of reducing the cooking loss to zero for poultry. Individuals often make gravy from chicken drippings or make chicken stock. DEP believes that the risk assessment should assume a cooking loss of zero for poultry.

Wild Edible Plants. The report should discuss uncertainties associated with fiddlehead fern analysis. Given the limited fiddlehead fern sampling, DEP believes it is appropriate to use the maximum detected concentration rather than the mean.

Future Agricultural Use. In the July 1997 comments, the agencies commented that the risk assessment should not assume that farming activities are limited to two current farms located upstream of Woods Pond. DEP still believes that farming activity must be considered a reasonably foreseeable use in any area, unless there is a clear limitation on farming uses. The likelihood of converting land in different areas to agricultural use in the future should be evaluated separately for different types of agriculture (for example, dairy farming, which should include exposure to home-produced meat, produce farming, chicken farming, egg production). The risk assessment should systematically identify and map floodplain areas where each type of agricultural use is reasonably foreseeable, and should provide justification for excluding the remaining areas.

Cattle Sediment Exposure. It is unclear whether sediment exposure is included in tissue concentration estimates for cattle. If a "vegetative buffer" is the only barrier between cattle and the river, then a RME scenario should include some exposure to river sediment.

Future small-scale backyard animal operations. The risk assessment should identify areas where future small-scale backyard animal operations could occur. The risk assessment should then determine risks for these properties.

Cumulative Risks. It is unclear whether cumulative cancer risks will be calculated for consumption of a combination of farm-raised livestock and produce, although it is likely that farmers will have a tendency to consume a combination of home-grown items. The uncertainty analysis should provide risks for combined exposure pathways.

DEP appreciates the opportunity to present the above review comments to the panel for its consideration.

Sincerely,

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SJS/sjs
Attachment

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Commissioner of Health, City of Pittsfield

Boards of Health: Lenox, Lee, Stockbridge, Great Barrington, Sheffield
Housatonic River Initiative
Public Information Repositories
Site File: GECD850

ATTACHMENT A

References

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